

REMARKS

In order to expedite prosecution of this application, claim 18 has been amended. The claims in the present application very clearly avoid all of the prior art references, whether taken singly or in combination with each other, and these claims should be allowed.

As set forth in claim 1, for example, applicant's invention concerns a bi-directional steerable guidewire having a deflectable tip. An elongated flexible tubing is provided, having proximal and distal portions. A flexible helical coil is provided, having multiple turns and having proximal and distal ends. The helical coil has a rectangular cross sectional configuration and has continuous undulations. The undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil. The proximal end of the helical coil is attached to the distal portion of the flexible tubing. The undulations are lateral to the length of the elongated flexible tubing.

An elongated deflection member is provided, having proximal and distal portions. The deflection member is slidably disposed within the tubing and within the helical coil. The distal portions of the deflection member are flattened to form a deflection ribbon which extends in a plane.

A retaining ribbon is provided having proximal and distal ends. The proximal end of the retaining ribbon is attached to the distal portion of the flexible tubing. The retaining ribbon is oriented to extend in a plane which is generally parallel to the plane of the deflection ribbon.

An attachment member engages the distal end of the helical coil, the distal portion of the deflection member and the distal end of the retaining ribbon. In this

manner, longitudinal movement of the deflection member in a distal direction causes the distal end of the helical coil to be deflected in one direction, and longitudinal movement of the deflection member in a proximal direction causes the distal end of the helical coil to deflect in another opposite direction.

Contrary to the Examiner's statements in the Office Action, Gambale is significantly different in structure from applicant's claimed invention. The Examiner states that Gambale comprises an elongated flexible **shaft** 32. This is irrelevant. Applicant's claims call for elongated flexible **tubing**, not a flexible **shaft**. Gambale's flexible helical spring 42 is an inner safety spring which forms the inner tubing. Safety spring 42 does not have continuous interlocking undulations as claimed nor is there any disclosure of any interlocking undulations.

Gambale's guidewire is significantly structurally different from applicant's guidewire. Gambale has an outer spring 24 and an inner safety spring 42, and item 62 of Gambale is not a "ribbon" but is instead a solid wire having a circular cross sectional configuration (see Fig. 4B). It is located only at the proximal end of the entire guidewire section (see Fig. 4). Further, in Gambale, the deflection member 46 is **outside** the "tubing" (spring 42); not within the tubing as set forth in applicant's claims 1 and 23.

It can be seen that Gambale lacks many of the structural elements set forth in applicant's claims. Gambale does not disclose the elongated flexible tubing as claimed. Gambale does not disclose the helical coil having a rectangular cross sectional configuration as claimed. Gambale does not disclose the helical coil having continuous undulations wherein the undulations of adjacent turns interlock with each other. Gambale does not disclose undulations which are lateral to the length of elongated

flexible tubing. Gambale does not disclose a retaining ribbon attached to the distal portion of any flexible tubing. Gambale does not disclose a retaining ribbon that is oriented to extend in a plane that is generally parallel to the plane of a deflection ribbon.

The Examiner recognizes that Gambale does not disclose a flexible helical coil having interlocking undulations disposed lateral to the length of the flexible tubing and that Gambale does not dispose the windings of the helical coil in such a manner as to create a square or a sine wave profile. The Examiner has combined Gambale with Mirigian but this combination does not disclose, suggest or teach applicant's invention as claimed. In addition to Gambale lacking numerous elements set forth in applicant's claims, Mirigian does not remedy the deficiency of a helical coil having a rectangular cross sectional configuration and having continuous undulations wherein the undulations of adjacent turns interlock with each other and with the undulations being lateral to the length of the elongated flexible tubing.

Mirigian does not disclose a helical coil having a rectangular cross sectional configuration and having continuous undulations as claimed. It can be seen that each of segments 32 of Mirigian ***is a separate and discrete structure, independent from any adjacent segment or segments***. It is not a helical coil. This is contrary to applicant's claimed helical coil having continuous interlocking undulations. Mirigian teaches away from a helical coil having continuous interlocking undulations, as claimed, by expressly reciting that segments 32 are **individual, and are separate and discrete structures**, and that "each of segments 32 is typically a separate and discrete structure, independent from any adjacent segment or segments." (Paragraph [0026]).

In fact, when Mirigian discloses a structure that is not made up of separate and discrete segments 32 that are independent from any adjacent segment or segments, Mirigian uses mere notches 444 (see Fig. 11) which are axially spaced and are not undulations nor are they anything even resembling undulations as claimed. This emphasizes how Mirigian teaches away from a helical coil having a rectangular cross sectional configuration and having continuous undulations which interlock with each other as claimed.

Thus it can be seen that not only is Gambale lacking in disclosing many of the structural features set forth in applicant's claims, but even Gambale combined with Mirigian does not remedy these significant deficiencies. Further, Mirigian is not physically combinable with Gambale because Mirigian's individual interlocking segments 32, which make up a hollow structure, are taught as being used in a simple guidewire construction having a core wire 12 extending therethrough and would not be applicable to the complex guidewire structure of Gambale which includes an outer spring 24 and inner safety spring 42.

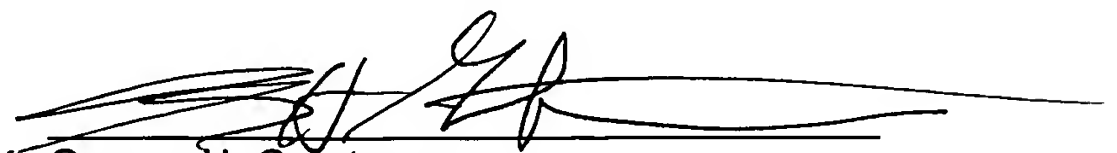
Further, the Examiner refers to item 62 of Gambale as "a retaining ribbon" but it is respectfully pointed out that item 42 of Gambale is not a "ribbon". It is solid wire having a circular cross section and is located only at the proximal end of the entire guidewire system.

None of the other prior art references, including Schaer et al., Hayzelden et al., and Palermo are properly combinable with Gambale to disclose applicant's invention as claimed. None of these references disclose, teach or even suggest a steerable guidewire including a helical coil having a rectangular cross sectional configuration and

having continuous undulations wherein the undulations of adjacent turns interlock with each other with the undulations being lateral to the length of the elongated flexible tubing. For the reasons set forth above, even if Gambale were combined with these other references, which combination would be improper, applicant's invention as claimed would not be disclosed, taught or even suggested.

Applicant's claims have been carefully drafted to very clearly distinguish applicant's invention from the prior art references, whether taken singly or in combination with each other. The Examiner's rejections in the June 16, 2006 Office Action are erroneous in that they overlook the numerous structural elements of applicant's claims that are not disclosed in the prior art. Further, the combinations of references in the Office Action are based on improper hindsight after reading applicant's own disclosure. Most significantly, even if combined, these references do not teach applicant's invention as claimed. For the foregoing reasons, it is clear that the present claims are allowable and an early notice of allowance is respectfully requested.

Respectfully submitted,
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A handwritten signature in black ink, appearing to read 'G. Gerstman', is written over a horizontal line.

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Date: Sept 7, 2006